

wherein

$$Y = \frac{[\text{Glucose}]_{\text{measured at } 23^{\circ}\text{C}} - [\text{Glucose}]_{\text{measured at } T^{\circ}\text{C}}}{[\text{Glucose}]_{\text{measured at } T^{\circ}\text{C}}}$$

In order to calculate the value of K, each of a multiplicity of glucose concentrations is measured by the meter at various temperatures, T, and at 23° C. (the base case). Next, a linear regression of Y on T-23 is performed. The value of K is the slope of this regression.

Various features of the present invention may be incorporated into other electrochemical test strips, such as those disclosed in U.S. Pat. Nos. 5,120,420; 5,141,868; 5,437,999; 5,192,415; 5,264,103; and 5,575,895, the disclosures of which are hereby incorporated by reference.

We claim:

1. A test strip, having an indentation along an edge for tactile identification of a sample application port, said test strip comprising:

a first insulating substrate having first and second surfaces, an indentation along an edge and a vent hole; at least two electrically conductive tracks affixed to the first surface of the first insulating substrate;

a second insulating substrate having first and second surfaces, an indentation along an edge, and first and second openings, the second surface being affixed to the conductive tracks and the first surface of the first insulating substrate, the first opening exposing a portion of the conductive tracks for electrical connection to a meter capable of measuring an electrical property, the second opening being located along said edge and exposing a different portion of the conductive tracks and the vent hole;

a test reagent overlaying at least a portion of the conductive tracks exposed by the second opening; and

a roof having first and second surfaces and an indentation along an edge, the second surface of the roof being affixed to the first surface of the second insulating substrate and positioned so that the second surface of the roof and the surface of the first insulating substrate form opposing walls of a capillary fill chamber with a sample application port at said edge of the second insulating substrate, wherein the second opening in the second insulating substrate and the indentations in the first insulating substrate, the second insulating substrate, and the roof are aligned to thereby provide for tactile identification of the sample application port.

2. The test strip of claim 1, wherein the second surface of the roof includes a hydrophilic coating.

3. The test strip of claim 1, wherein the test reagent includes

reaction components appropriate for performing a test and from about 1.75% by weight to about 17.5% by weight polyethylene oxide having a mean molecular weight from about 100 kilodaltons to about 900 kilodaltons, wherein the reagent will redissolve or resuspend upon addition of an aqueous test sample to the reagent.

4. The test strip of claim 1, wherein the test reagent includes reaction components appropriate for performing a test, and a dissolvable or suspendable film forming mixture including from about 0.2% by weight to about 2% by weight polyethylene oxide having a mean molecular weight from about 100 kilodaltons to about 900 kilodaltons,

wherein the test reagent may be applied to the test strip in a wet form, may be subsequently dried, and then

redissolved or resuspended upon addition of an aqueous test sample to the dried reagent.

5. The test strip of claim 4, wherein the second surface of the roof includes a hydrophilic coating.

6. The test strip of claim 1, wherein the roof has a solid transparent or translucent window, which is dimensioned and positioned so that the window overlays the entire width of the electrically conductive track that is closest to the indentation of the first insulating substrate and at least about ten percent of the width of the other electrically conductive track.

7. The test strip of claim 6, wherein the second surface of the roof includes a hydrophilic coating.

8. The test strip of claim 6, wherein the test reagent includes

reaction components appropriate for performing a test and from about 1.75% by weight to about 17.5% by weight polyethylene oxide having a mean molecular weight from about 100 kilodaltons to about 900 kilodaltons, wherein the reagent will redissolve or resuspend upon addition of an aqueous test sample to the reagent.

9. The test strip of claim 6, wherein the test reagent includes reaction components appropriate for performing a test, and a dissolvable or suspendable film forming mixture including from about 0.2% by weight to about 2% by weight polyethylene oxide having a mean molecular weight from about 100 kilodaltons to about 900 kilodaltons,

wherein the test reagent may be applied to the test strip in a wet form, may be subsequently dried, and then redissolved or resuspended upon addition of an aqueous test sample to the dried reagent.

10. The test strip of claim 9, wherein the second surface of the roof includes a hydrophilic coating.

11. The test strip of claim 1, further comprising:

a first notch along the indentation in the first insulating substrate, and a notch along the indentation in the roof, both first and second notches being positioned so that they overlay one another.

12. The test strip of claim 11, wherein the second surface of the roof includes a hydrophilic coating.

13. The test strip of claim 11, wherein the test reagent includes

reaction components appropriate for performing a test and from about 1.75% by weight to about 17.5% by weight polyethylene oxide having a mean molecular weight from about 100 kilodaltons to about 900 kilodaltons, wherein the reagent will redissolve or resuspend upon addition of an aqueous test sample to the reagent.

14. The test strip of claim 11, wherein the test reagent includes reaction components appropriate for performing a test, and a dissolvable or suspendable film forming mixture including from about 0.2% by weight to about 2% by weight polyethylene oxide having a mean molecular weight from about 100 kilodaltons to about 900 kilodaltons,

wherein the test reagent may be applied to the test strip in a wet form, may be subsequently dried, and then redissolved or resuspended upon addition of an aqueous test sample to the dried reagent.

15. The test strip of claim 14, wherein the second surface of the roof includes a hydrophilic coating.

16. The test strip of claim 11 wherein the roof has a solid transparent or translucent window, which is dimensioned and positioned so that the window overlays the entire width of the electrically conductive track that is closest to the indentation of the first insulating substrate and at least about ten percent of the width of the other electrically conductive track.

17. The test strip of claim 16, wherein the second surface of the roof includes a hydrophilic coating.

18. The test strip of claim 16, wherein the test reagent includes reaction components appropriate for performing a test, and a dissolvable or suspendable film forming mixture including from about 0.2% by weight to about 2% by weight polyethylene oxide having a mean molecular weight from about 100 kilodaltons to about 900 kilodaltons,

wherein the test reagent may be applied to the test strip in a wet form, may be subsequently dried, and then redissolved or resuspended upon addition of an aqueous test sample to the dried reagent.

19. The test strip of claim 18, wherein the second surface of the roof includes a hydrophilic coating.

20. The test strip of claim 16, wherein the test reagent includes reaction components appropriate for the test, and a dissolvable or suspendable film forming mixture including from about 0.2% weight to about 2% by weight polyethylene oxide having a mean molecular weight of 300 kilodaltons.

21. The test strip of claim 20, wherein the polyethylene oxide is about 0.71% by weight.

22. The test strip of claim 16, wherein the test reagent includes

reaction components appropriate for performing a test and from about 1.75% by weight to about 17.5% by weight polyethylene oxide having a mean molecular weight from about 100 kilodaltons to about 900 kilodaltons,

wherein the reagent will redissolve or resuspend upon addition of an aqueous test sample to the reagent.

23. The test strip of claim 22, wherein the mean molecular weight of the polyethylene oxide is 300 kilodaltons.

24. The test strip of claim 23, wherein the amount of polyethylene oxide, in the reagent is about 6.2% by weight.

25. A test strip comprising:

a first insulating substrate having first and second surfaces, a notch along an edge, and a vent hole;

at least two electrically conductive tracks affixed to the first surface of the first insulating substrate;

a second insulating substrate having first and second surfaces and first and second openings, the second surface being affixed to the conductive tracks and the first surface of the first insulating substrate, the first opening exposing a portion of the conductive tracks for electrical connection to a meter capable of measuring an electrical property, the second opening being located along an edge of the second insulating substrate and exposing a different portion of the conductive tracks, the notch in the first insulating substrate, and the vent hole;

a test reagent overlaying at least a portion of the conductive tracks exposed by the second opening; and

a roof having first and second surfaces and a notch along an edge, the second surface of the roof being affixed to the first surface of the second insulating substrate and positioned so that 1) the second surface of the roof and the first surface of the first insulating substrate form opposing walls of a capillary fill chamber with a sample application port at said edge of the second insulating substrate, and 2) the notch in the roof overlays the notch in the first insulating substrate;

whereby the notch in the roof and the notch in the first insulating substrate will cause a liquid aqueous sample, when touched to the sample application port, to flow into the capillary chamber without significant hesitation.

26. A test strip, comprising:

a first insulating substrate having first and second surfaces and a vent hole;

at least two electrically conductive tracks affixed to the first surface of the first insulating substrate;

a second insulating substrate having first and second surfaces and first and second openings, the second surface being affixed to the conductive tracks and the first surface of the first insulating substrate, the first opening exposing a portion of the conductive tracks for electrical connection to a meter capable of measuring an electrical property, the second opening being located along an edge of the second insulating substrate and exposing a different portion of the conductive tracks and the vent hole;

a test reagent overlaying at least a portion of the conductive tracks exposed by the second opening; and

a roof having first and second surfaces and a solid transparent or translucent window, the second surface of the roof being affixed to the first surface of the second insulating substrate and positioned so that it overlays the second opening of the second insulating substrate and so that the second surface of the roof and the first surface of the first insulating substrate form opposing walls of a capillary fill chamber with a sample application port at said edge of the second insulating substrate, and the transparent or translucent window being dimensioned and positioned so that the window extends from the sample application port, and overlays the entire width of one of the electrically conductive tracks and at least about ten percent of the width of the other electrically conductive track.

27. A test strip, having an indentation along an edge for tactile identification of a sample application port, said test strip comprising:

a first insulating substrate having first and second surfaces and an indentation along an edge;

at least two electrically conductive tracks affixed to the first surface of the first insulating substrate;

a second insulating substrate having first and second surfaces, an indentation along an edge and an opening, the second surface being affixed to the conductive tracks and the first surface of the first insulating substrate, the second insulating substrate configured to expose a portion of the conductive tracks for electrical connection to a meter capable of measuring an electrical property, the opening being located along said edge and exposing a different portion of the conductive tracks;

a test reagent overlaying at least a portion of the conductive tracks exposed by the opening;

a roof having first and second surfaces and an indentation along an edge, the second surface of the roof being affixed to the first surface of the second insulating substrate and positioned so as to overlay the opening and so that the second surface of the roof and the first surface of the first insulating substrate form opposing walls of a capillary fill chamber with a sample application port at said edge of the second insulating substrate; and

a vent hole communicating with the capillary fill chamber;

wherein the opening in the second insulating substrate and the indentations in the first insulating substrate, the second insulating substrate, and the roof are aligned to

15

thereby provide for tactile identification of the sample application port.

28. The test strip of claim 27, wherein the roof has a solid transparent or translucent window, which is dimensioned and positioned so that the window overlays the entire width of the electrically conductive track that is closest to the indentation of the first insulating substrate and at least about ten percent of the width of the other electrically conductive track.

29. The test strip of claim 27 further comprising a first notch along the indentation of the first insulating substrate, and a notch along the indentation in the roof, both first and second notches being positioned so that they overlay one another.

30. The test strip of claim 29 wherein the roof has a solid transparent or translucent window, which is dimensioned and positioned so that the window overlays the entire width of the electrically conductive track that is closest to the indentation of the first insulating substrate and at least about ten percent of the width of the other electrically conductive track.

31. A test strip comprising:

a first insulating substrate having first and second surfaces and a notch along an edge;

at least two electrically conductive tracks affixed to the first surface of the first insulating substrate;

a second insulating substrate having first and second surfaces and an opening, the second surface being affixed to the conductive tracks and the first surface of the first insulating substrate, the second insulating substrate configured to expose a portion of the conductive tracks for electrical connection to a meter capable of measuring an electrical property, the opening being located along an edge of the second insulating substrate and exposing a different portion of the conductive tracks, aid overlaying the notch in the first insulating substrate;

a test reagent overlaying at least a portion of the conductive tracks exposed by the opening;

a roof having first and second surfaces and a notch along an edge, the second surface of the roof being affixed to the first surface of the second insulating substrate and positioned so that 1) the second surface of the roof and the first surface of the first insulating substrate form opposing walls of a capillary fill chamber with a sample

16

application port at said edge of the second insulating substrate, and 2) the notch in the roof overlays the notch in the first insulating substrate; and

a vent hole communicating with the capillary fill chamber;

whereby the notch in the roof and the notch in the first insulating substrate will cause a liquid aqueous sample, when touched to the sample application port, to flow into the capillary chamber without significant hesitation.

32. A test strip comprising:

a first insulating substrate having first and second surfaces;

at least two electrically conductive tracks affixed to the first surface of the first insulating substrate;

a second insulating substrate having first and second surfaces and an opening, the second surface being affixed to the conductive tracks and the first surface of the first insulating substrate, the second insulating substrate configured to expose a portion of the conductive tracks for electrical connection to a meter capable of measuring an electrical property, the opening being located along an edge of the second insulating substrate and exposing a different portion of the conductive tracks;

a test reagent overlaying at least a portion of the conductive tracks exposed by the opening;

a roof having first and second surfaces and a solid transparent or translucent window, the second surface of the roof being affixed to the first surface of the second insulating substrate and positioned so that it overlays the opening of the second insulating substrate and so that the second surface of the roof and the first surface of the first insulating substrate form opposing walls of a capillary fill chamber with a sample application port at said edge of the second insulating substrate, and the transparent or translucent window being dimensioned and positioned so that the window extends from the sample application port, and overlays the entire width of one of the electrically conductive tracks and at least about ten percent of the width of the other electrically conductive track; and

a vent hole communicating with the capillary fill chamber.

\* \* \* \* \*